CHAPTER V: MANIPULATIVE AND BODY-BASED THERAPIES: CHIROPRACTIC AND SPINAL MANIPULATION

Efficacy of Spinal Manipulation and Mobilization

Let's turn now to evidence for effectiveness, because what we're really dealing with, with all sorts of medical procedures, is whether or not the benefit exceeds the risk. We need evidence for that. In science, we like to talk about the hierarchy of evidence, starting with perhaps—and another person might put a slightly different hierarchy here—meta-analyses, which is one very high form of summarizing lots of results. Then, we have randomized controlled trials. We have quasi-experimental studies. We have observation studies, case reports, clinical observations, and anecdotes. Lower down on the pyramid, there is a much greater preponderance of the evidence. As we get closer to the top, because of the complexity and the money involved, we have much less of that sort of evidence.

We now have over 90 randomized trials of manipulation and mobilization. Most of those are on back pain, many on neck pain, some on headache, and only 11 trials for every other condition you might imagine—not very many at all. Manipulation has been compared with placebos, exercise and advice, no treatment, back school, analgesics, nonsteroidals, and a variety of other things, in different studies. Let's take a look at some of these things now, and low back pain because this is where we see most of our work.

This is actually a study done by a colleague of mine, Dan Churkin, who's in the State of Washington and also a highly funded investigator by the NIH, and a wonderful person, by the way. He did a study a few years ago, and I'm going to use this to illustrate what a randomized controlled trial kind of looks like. What he decided to do was compare a physical therapy modality called MacKenzie Therapy with chiropractic manipulation, or CM, and a little booklet that simply told people about their back pain and how they could take care of themselves at home. This was all done within the context of a health

maintenance organization in the State of Washington. It was what we would basically call a pragmatic, single-blind, 3-group, prospective randomized control trial.

Pragmatic in the sense that the chiropractors in this study, and the physical therapists in this study, were basically allowed to do the best job they thought they could do for each patient that was in the study. They weren't restricted or limited to doing one specific thing on every patient that walked in the door. They were allowed to vary what they could do in order to get the best effect, and we could still make those comparisons. So, there is some mixing within each one of the groups, but we could still compare the groups. It was pragmatic in that sense. It was single blind in the sense that the outcomes were blinded. It's hard by the way to do a randomized trial blinding a chiropractor. They like to see what they're going to do and they also tend to know what they're doing. So it's like doing a randomized trial with surgery. It's very difficult to do, so you don't have very many double-blind or triple-blind studies with these forms of care. It can be done under very specific circumstances but not generally speaking. But the person that was assessing the outcomes for the patients didn't know which treatment the patients were getting. So, in that sense, it was a blinded study.

All these patients had persistent back pain that was greater than 7 days. In fact, I think the average back pain in this study was several months old. They had 1 month of care, 1 month of care for the chiropractors, 1 month of care for the MacKenzie treatment. They were also given this booklet by their primary care physician at the HMO and basically told to go home. That was the cure for that. Then they measured the outcomes of the patients at 1 week, 4 weeks, 12 weeks, at 1 year and 2 years hence. The major outcome that they measured in these patients was low back pain symptoms and what we would call pain-related disability. So, this is a nice experimental study comparing one form of care with another, to what, conceivably, might be called a control treatment, which is this back pain booklet. But other people might conceive it as a back school education, a form of education or cognitive therapy. There's some argument about what that really represents.

Well, this is a graph of one of the outcome measurements here, to show you what we look at when we try to interpret the results of a clinical trial. Over here on the left, we had a scale of symptoms. In this case, it was the bothersomeness scale. That's kind of a mouthful. Bothersome symptoms, with 0 being no bother at all, with 10 being quite bothersome. Down here, we have the time, we have 1 month, 3 months, and here we have 12 months. So, that's the setup for you.

You can see the 3 treatment groups. They're all bunched together right here at the beginning. There are 3 little characters there. Those will separate out as we move here. But they all started off with symptoms around the level of a 6. So, at the first month of follow-up, you can tell that 2 of the groups are kind of close together and 1 of the groups is not quite doing as well as those 1 groups. When we did some inferential statistical testing, it was found that the *P* value was .02. Now what that means is that there are only 2 chances out of 100 that these results would have happened by chance like that, the separation. Thus, the difference that we see here is probably real and not due simply to random variability. Statistics is a little more complicated than that, but I'm not qualified to tell you much more than that.

This is what happened at 3 months, and there again we have a *P* value of .06. Now you should know there's convention in statistics that if it's greater than .05, there's a chance that the differences may not be real. In fact, they may be due to chance and, therefore, we can't really conclude that the differences we see here are, in fact, real. They might be due to chance. There are at least 6 chances out of 100 that that might be true in this particular study. Then we have the results at 1 year and, again, the *P* value was .16. Clearly, there's a chance that this difference here could have happened by chance. But you can see that there's some separation here, they started together, they separated, and there's still some separation.

Now, of course, what you want to know is—because you're blinded right now— which one of these is which. We'll put some lines on here to give you some sort of trend, to give you kind of an idea. You can tell that people's back pain tends to recover very quickly,

within a month—but maybe not completely, and certainly not completely at 3 months, and certainly not necessarily completely at even a year later. But they certainly are better off than where they started. This is a very typical pattern that we see in back pain research. But here's the key right here. The booklet was this one right here. The MacKenzie Therapy—the physical therapy treatment—was right here. The chiropractic treatments, spinal manipulation was the blue line right here.

Now the question that we all are facing, which is, how do we interpret these results? Are the differences real here, in favor of the 2 physical treatments? Certainly, they appear to be. Certainly, they might appear to be here, too. Here, I don't think it's as clear and the statistics kind of bears that out. What we need to ask ourselves is, well, even if these differences are real, here and here, is the difference there clinically important? Is that difference between the booklet and the therapies large enough to be important to make a difference? Thus, should we spend the money that it took on the therapist, the chiropractors, and the physical therapists here, as opposed to handing out a 10-page booklet, which costs about $1.25?

This is a health services question. It is not an easy question. Certainly, I can tell you this. If you were the patient in this study, I can tell you that you were much more satisfied with the care you got from the physical therapist and from the chiropractor. You were not very happy with your HMO when you went in with a back pain problem and they said, "Well, it'll go away on its own, here have a booklet." Because that's essentially what they did. The satisfaction rates that were actually measured were about triple in these 2 groups compared with here. The question remains though, is the greater level of satisfaction for patients worth the extra cost that it took to go to the chiropractor or the physical therapist? This is not an unusual pattern that we are seeing in lots of the trials on spinal manipulation. In fact, this is a pattern we're seeing in almost every clinical trial for every type of therapy, for back pain, right now.

I'm sorry for taking so long to explain that particular clinical trial to you but I think it represents, it shows you the kind of thing that we're faced with, in trying to interpret the

results of clinical trials in this area. Now, when we lump all those trials together, all those on back pain anyway, the 45 or so that exist on back pain, and do a systematic review, looking at all the trials with one technical eye, we kind of see these kinds of conclusions.

This mirrors the confusion that I just represented to you in that one single study because I was involved with a meta-analysis back in 1992, and we said that manipulation was pretty good stuff. Paul Shekelle of the Rand Corporation said "it was pretty good stuff" also. But Coos, in 1996, said, "The efficacy is not demonstrated in high-quality randomized trials." Gert Bronfort then disagreed a year later and said, "Yes, but there's moderate strength of evidence of acute and chronic back pain." Then Maurits W van Tulder said, "Yes, it's okay for chronic back pain but not for acute low back pain." This is all interpreting the same body of evidence. So, if you think lay people have problems figuring out what's going on in science, so do the scientists, sometimes.

This is an example, by the way, of a meta-analysis. This was done by the Rand Corporation. These are individual clinical trials here and there are 7 of them I believe. These are showing the benefit of manipulation compared with the other thing. If that line right here is here to the right of this line, that indicates an effect that's positive, except there is some doubt because, statistically speaking, it might have been due to chance right there. These are means, they're averages actually for these groups. When you add these averages up, for all these studies, you get an average average, so to speak, that is above, statistically speaking, this line that does favor manipulation. That's the value of doing a statistical meta-analysis. Now, there's been other meta-analyses done subsequent to 1992 that have not been quite this clear. But that gives you an example of what's going on.

But then the U.S., the U.K., Denmark, and Sweden all put together back pain guidelines to the National Consensus process. The U.S. guidelines decided that there was evidence for manipulation for acute back pain but not for chronic. They didn't deal with chronic at all, in fact, in the process. The U.K. guidelines said that there was evidence for acute back pain, but they didn't talk about chronic back pain. The Danish guidelines said there was evidence for both acute and chronic, and the Swedish guidelines said the same thing.

So, again, this is reflecting a kind of consensus, a scientific consensus of where we are with this particular therapy, at least from a health services point of view. I think, particularly because in comparison with a lot of other things, there was more research on this particular procedure than there is for almost anything else for back pain. Which isn't to say that there's a lot of great definitive research so far.

Some of the recent randomized control trials look something like this. But these sorts of things still leave us kind of in the middle asking, what is really going on here with this form of therapy? For neck pain and headache, the summary breaks down like this. For acute neck pain, you can see here that the positives don't outweigh the question marks. In parentheses, it's a very qualified, "Well, we think there's some value there, but we're not really sure," and the not applicables. In fact, there are virtually no randomized trials in manipulation or mobilization for acute neck pain. I think there are 3 for mobilization and that's all.

For chronic neck pain, however, there are more trials and, as you can see, there's more evidence. So, it looks like there is some evidence for chronic neck pain. In terms of headache, you can see here that where the guidelines have actually decided to make a decision, and they didn't even decide, they decided not to decide here, you can see that the evidence is very positive. So, it looks like for common forms of headache—cervicogenic headache, muscle tension headache, and perhaps even some cases of migraine—cervical adjustments, in fact, might be very beneficial.

Here are some recent randomized trials. In this case, for acute or chronic neck pain, physical therapy was a little bit better than chiropractic care, in this one study. In this study, of 119 patients, manipulation was the same as exercise, which is the same as physical therapy—no differences at all there. They all worked very well. In Bronfort's trial, spinal manipulation plus exercise was more effective than manipulation by itself, which makes some physiological sense. In this study of acute and chronic neck pain, mobilization was better than physical therapy, which was also better than just going to a general practitioner. But this study was done in the Netherlands, and we don't know how

it might apply here in the U.S. That basically concludes the research on musculoskeletal conditions and spinal manipulation/mobilization for low back pain, neck pain, and headache, which represents the bulk of the trials.

What we have now is other conditions. I'm going to summarize this rather rapidly. When looked at in 1997 by Bronfort, it became clear that there are not enough trials and the ones that exist are not very well done. They need to be larger. They need to be more complex. They need to be more carefully controlled. Manipulation is not superior to placebo manipulation for hypertension, for dysmenorrhea, or for chronic asthma in adults when combined with medical management. There is one study indicating that manipulation was superior to placebo for infantile colic and yet, a later study indicated that it was not. So we're left again in the middle there. Maria Hondras, in 2000, looked at manipulation for asthma, and she said then that there is insufficient evidence to support the use of manual therapies for patients with asthma.

So that really brings us to kind of a conclusion of the science in this area because we have a lot of work to do still. I guess I should say too that the science that we're seeing here might not reflect patient's experiences. Because, very clearly, when we do randomized control trials—and this is one of the problems that medical science has to deal with—we tend to average the results together. I've never seen an average patient; I mean very few of you are average, you know. I don't think I'm average anyway. When we go to see a physician, any kind of health care provider, we expect to be treated as an individual.

What clinical trials, and a lot of other epidemiological studies, do is, they tend to lump people together and put them in categories because that's the easiest and the best way to make sense of a very large amount of information and to try to summarize it and allow us to come up with probabilities. So, if we find out that's there only a 50% chance that any form of care is going to be beneficial for any given patient, when you walk into an office and ask for that care, you've got a 50-50 chance—a 50% that it may not help you and a 50% chance that it might help you. If nothing else is helping you, and you're satisfied

with the provider that you've been seeing and you like what's been going on, then you're going to take that 50% chance because you might just be helped.

So, looking at patients' individual experiences, and the reasons they have those individual experiences, is something that we have not tackled very well yet as scientists. That is why I think that the next wave of research, in the CAM world, is going to be in behavioral medicine, psychology, anthropology, and sociology. In those disciplines, we're going to find out some very interesting things about what health care really is all about for individuals. When we learn about those things and can merge them into the knowledge we've got—very sophisticated knowledge about the way the body works, chemically, and neurologically and all other ways—we're really going to have a handle, I hope, on the way we can really help people.